

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s):	Kokubo et al.		
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Title:	SOLID PREPARATION COATED WITH A FILM COATING LAYER AND FILM COATING AGENT		

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APPEAL BRIEF UNDER 37 CFR § 41.37

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed January 10, 2007, and the Notice of Non-Compliant Appeal Brief mailed April 30, 2007.

1. ***Real Party in Interest.***

The real party in interest in this appeal is Shin-Etsu Chemical Co., the assignee of the above-referenced patent application.

2. ***Related Appeals and Interferences.***

There are no related appeals and/or interferences involving this application or its subject matter.

3. ***Status of Claims.***

Claims 6 – 9, 11, 13 – 20, and 31 – 47 are pending and all claims stand rejected as unpatentable over a combination of references as set forth in greater detail below. The prior art rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 is appealed herein.

Claims 1 – 5, 10, 12, and 21 – 30 have been cancelled.

4. ***Status of Amendments.***

No claims were filed subsequent to the Final Office Action.

5. ***Summary of Claimed Subject Matter.***

The present invention as embodied in independent Claims 31 and 33 is directed to a solid preparation having a continuous multicolored coating layer. The continuous multicolored coating is provided by coating a solid preparation with a continuous coating layer having one or more colorants. Portions of the coating layer are then selectively exposed to radiation, such as light, in an amount that is sufficient to cause a change in color in the colorants that are exposed to the radiation.

By way of background, it is increasingly desirable to distinguish different medicines from each other based on color, size, or shape. This is particularly true in view of the aging population and the number of patients who must take multiple medicines. For example, distinguishing medicines from one another is very important in order to prevent mistakenly administering or consuming the incorrect medicine.

Many medicines are available as solid preparations that can be ingested. Two common forms of such solid preparations include capsules and tablets. Generally, tablets comprise a powder medicine that has been compressed into a desired shape. Capsules on the other hand generally include a two piece outer shell in which the medicine is disposed. The pieces of the outer shell, also referred to as caps, comprise a dissolvable film. The caps comprising the outer shell are often a different color from each other so that the resulting capsule is multicolored. Multicolored solid preparations are desirable because they help facilitate easy identification and can also be used by manufactures in branding their particular product. Capsules have gained

popularity due to their ease on ingestion, lack of unpleasant taste that can often be associated with tablets, and the ability to be produced to have two or more colorings.

In the early 1980's it was learned that the two-piece outer shell of the capsules were susceptible to tampering. As a result, many pharmaceutical makers chose to provide solid preparations in the form of tablets to prevent tampering. To maintain many of the desirable properties of capsules, a film coating is applied to the tablets. However, the coatings of the film-coated tablets had only a single color and did not have the desirable multicolor shells that were available in capsules. To provide a multicolored coated tablet, various methods have been developed. For example, coated tablets have been produced in which two tableting powders having different colors are compressed together to make a multicolored tablet. However, the resulting coated tablets tend to be weakened and crack at the interface of the powders. Other methods include dipping a pre-coated tablet in two different film solutions having different colors. Typically, this process requires specialized equipments and complicated steps. As a result, the prior art has not provided a simple and efficient means of providing multicolored tablets/pills.

The invention defined in independent Claims 31 and 33 is directed to a solid preparation having a continuous multicolored coating layer. See page 9, lines 21 – 24 and FIG. 4, reference characters A and B. As discussed on page 9, lines 1 – 9, a solid preparation having a multicolored continuous coating layer overcomes many of the problems associated with prior art methods, such as low strength and inefficient or complex production process, as well as providing a solid preparation having two or more colors that helps facilitate distinguishability and identification of the solid preparation.

Independent Claim 31 recites a solid preparation having a multicolored continuous film coating layer. Claim 31 further recites that the solid preparation is formed by first coating a solid preparation with a coating layer having one or more colorants. See generally page 11 line 18 through page 13, line 25. In a subsequent step, a first part of the coating layer and a second part of the coating layer are irradiated with light in an amount that is sufficient to cause the first and second parts of the coating layer to have different colorations with respect to each other. For example, as discussed on page 19, lines 7 – 21, a first part of the solid preparation can be

irradiated with an amount of radiation that causes a color change in the first part, while the amount of radiation to which the second part of the solid preparation is exposed is insufficient to result in a color change. As a result, a solid preparation having a multicolored continuous film coating layer is provided.

Similarly, independent Claim 33 recites a solid preparation having a multicolored continuous coating layer that is created by changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer to the exclusion of the remainder of the coating. As discussed on page 18, lines 1 – 17, the multicolored continuous coating can be provided by irradiating a first region of the coating with light while shielding a second region of the coating from the light.

The claimed invention also advantageously provides a solid preparation that can have a continuous coating in which a pattern in the form of a bar code, logo, letters, and the like are created directly in the coating of the film without the requirement of an additional printing or engraving step. For example, a photomask having a desired pattern can be used to selectively shield a portion of the continuous coating from being irradiated with light so that exposure to a sufficient amount of irradiation forms the desired pattern in the continuous coating layer. See generally page 23, lines 1 – 19.

6. *Grounds of Rejection to be Reviewed on Appeal.*

Claims 6 – 9, 11, 13 – 17, and 31 – 44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,089,270 to Hampton et al. in view of U.S. Patent No. 3,409,570 to Dempski et al. Claims 18 – 20 and 45 – 47 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hampton in view of Dempski and further in view of U.S. Patent No. 5,464,631 to Hoover et al. The Office Action relies on Hampton for the teaching of a two-colored tablet having a clear outer coating and an inner core consisting of a first and second coloring agent. The Office Action relies on Dempski for teaching a tablet/pill having a dye stabilization that prevents fading of the coating due to exposure to light. The Examiner has taken the position that it would be obvious to incorporate the dye stabilization methods as taught in Dempski with the bi-layered, two-colored tablet of Hampton to produce the claimed invention.

7. *Argument.*

The Examiner has failed to make a prima facie case of obviousness because 1) the combination of references fails to teach each and every claim element and 2) because there is no motivation to combine the references. Specifically, the combination of references fails to teach a solid preparation having a continuous multicolored film coating layer. Further, the combination of the references fail to disclose or suggest the steps that are necessary to arrive at the claimed invention and therefore fail to disclose or suggest the claimed structure that is arrived at with the claimed method steps.

1. **The Combination of Hampton and Dempski Does Not Disclose or Suggest Each and Every Element of Independent Claim 31.**

Applicants respectfully submit that the combination of Hampton and Dempski fails to disclose or suggest the claimed invention. Specifically, the combination of the cited references fails to disclose or suggest any of the following:

- a. a solid preparation having a multicolored continuous film coating layer as recited in Claim 31; or
- b. the method steps recited in Claim 31 by which the claimed solid preparation having a multicolored continuous film coating layer is prepared.

a. A Solid Preparation having a Multicolored Continuous Coating.

The combination of the references fails to disclose or suggest a solid preparation having a multicolored continuous coating. Hampton describes a multicolored tablet that is coated with a clear coating. The multicoloration is achieved by combining a first powder material containing a first coloring agent with a second powder material containing a second coloring agent. The two powders are compressed to form a solid tablet having a demarcation line between the first material and the second material. See column 4, line 3 to column 5, line 20. The two-colored tablet is subsequently coated with a clear gelatin layer through which the color components of the core are visible. See column 5, lines 37 – 49. The gelatin layer is clear and is not

multicolored. The two color sections comprise the core of the tablet and are not part of the coating.

Dempski generally describes a method and dye for color stabilizing a film coating composition on a tablet or pill so that the colored film coating resists discoloration or fading when exposed to sunlight or ultraviolet light. Dempski describes a film coating that is mono-colored and that includes a specific chemical composition that “inhibits fading of the color contained therein.” See column 1, lines 47 – 50. In fact, the primary objective and purpose of Dempski is to provide a film coating for a tablet that prevents fading of the coloring in the film because such fading is undesirable. For example, Dempski states that [i]t is highly desirable psychologically for a pharmaceutical product, for example, to have a pleasing appearance ... [a] faded or speckled pill or tablet can have an unpleasant psychological effect. See column 1, lines 28 – 34. Dempski in further characterizing the undesirable nature of fading/speckling further states that “[p]atients in need of self-administrated medication will often avoid proper treatment if it appears unattractive to them.” See column 1, lines 36 – 38.

In contrast to the cited references, Claim 31 recites a solid composition having a multicolored continuous film coating layer. Hampton teaches a multicolored core; not a multicolored coating. As noted above, the coating of Hampton describes a clear coating. Dempski also fails to teach a multicolored coating. As noted above, Dempski teaches a coating that includes a single dye colorant and an agent to prevent fading or speckling of this single colored coating. Dempski does not teach a tablet, let alone a multicolored coating. This is further evident from the examples in which only a single colorant was included in the coating composition. Thus, Hampton and Dempski both fail to disclose or suggest a solid preparation having a multicolored continuous coating.

The Examiner alleges that it would be obvious to “incorporate the dye coating material stabilization methods which comprise the step of exposing pills or tables to sunlight or ultraviolet radiation taught by Dempski et al. within the multicharacteristic, bi-layered, two-color tablet of Hampton et al. if one would desire a color change effect observed in the tablet.” See page 5 of the Final Office Action dated October 13, 2006. However, the combination contemplated by the Examiner still fails to disclose or suggest the claimed invention. Hampton describes a tablet

having a clear coating and a multicolored core. Dempski on the other hand, teaches a film coating having color stabilized dye to prevent discoloration or speckling in the film coating. As a result, a tablet of Hampton utilizing the color stabilization dye of Dempski would not have a multicolored film coating. Rather, such a tablet would have the multicolored core of tablet of Hampton and an outer coating that is colored according to the color-stabilized dye that is part of the coating of Dempski. Indeed, Dempski teaches a coating that includes a dye and a compound that stabilizes the color of the coating so that the coating does not change color. See column 1, lines 44 – 56. Thus, the combination of Hampton and Dempski fails to teach the claimed invention because they do not disclose a solid preparation having a continuous multicolored film coating layer.

Further, exposing the tablet of Hampton to radiation in the absence of Dempski's stabilized coating would still fail to provide a solid preparation having a continuous multicolored film coating layer because the tablet of Hampton has a clear coating and does not include colorants in the film coating that would be subject to fading or discoloration. As a result, exposing the tablet of Hampton to radiation, such as light, would still result in a tablet having a multicolored core and a clear coating. In contrast, Claim 31 recites a solid preparation having a multicolored continuous film coating.

b. The combination of Hampton and Dempski fails to disclose or suggest the steps of exposing a first part of a coating having one or more colorants to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation to produce a multicolored continuous coating.

Claim 31 recites steps of exposing a first part of a coating having one or more colorants to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parties of the coating layer having different coloration. These steps are not disclosed or suggested by the combination of Hampton or Dempski. The Examiner alleges that Example 1 in Dempski describes the effects of exposure to UV radiation on various tablets/pills of Dempski. As discussed at column 3, lines 46 – 54 of Dempski, the samples that did not include the stabilization dye had various levels of

fading. However, none of the examples in Dempski describe a tablet having a multicolored coating as a result of exposure to UV light. Further, none of examples described in Dempski disclose the recited steps of 1) exposing a first part of a coating having one or more colorants to a first amount of radiation and 2) exposing a second part of the coating layer to a second amount of radiation. Since the examples of Dempski fail to disclose or suggest the steps recited in Claim 31, the examples also fail to disclose the multicolored continuous film coating that results from the recited method steps.

The Examiner has failed to ascertain the differences between the prior art and the claimed invention because the Examiner has narrowly focused on fading of coatings caused by UV light while completely ignoring structure of the claimed composition and the actual steps recited in the claims. Thus, the Examiner has failed to compare the actual teachings of the references to the claims and has therefore failed to follow the standard for making an obviousness rejection as articulated by the *Supreme Court in Graham v. John Deere*, 383 U.S. 1 (1966): i.e., ascertaining the differences between the prior art and the claims in issue. This is not the proper inquiry in making an obvious rejection.

For the reasons set forth above, Applicants respectfully submit that the combination of Hampton and Dempski fails to disclose or suggest each and every element recited in Claim 31. Applicants respectfully request that the Board overturn this rejection.

3. The Combination of Baines, Musow, and Applicants' Alleged Admissions Do Not Disclose or Suggest Each and Every Element of Independent Claim 33.

Similar to Claim 31, independent Claim 33 recites a solid preparation having a multicolored continuous film coating layer. Claim 33 further recites the step of changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer to the exclusion of the remainder of the coating layer. As discussed above, the combination of Hampton and Dempski fails to disclose or suggest a solid preparation having a multicolored continuous film coating layer. Accordingly, the combination fails to disclose or suggest the recited solid preparation for the same reasons stated above.

Further, neither Dempski nor Hampton teach the step of changing the coloration of one or

more parts of the coating layer by irradiating those parts of the coating layer to the exclusion of the remainder of the coating layer. As discussed above, Examiner alleges that Example 1 in Dempski describes the effects of exposure to UV radiation on various tablets/pills of Dempski. However, none of the examples in Dempski describe a tablet having a multicolored coating as a result of exposure to UV light. Further, none of examples described in Dempski disclose irradiating one or more parts of the coating layer to the exclusion of the remainder of the coating layer. Since the examples of Dempski fail to disclose or suggest the steps recited in Claim 33, the examples also fail to disclose the multicolored continuous film coating that results from the recited method steps.

For the reasons set forth above, Applicants respectfully submit that the combination of Hampton and Dempski fails to disclose or suggest each and every element recited in Claim 33. Applicants respectfully request that the Board overturn this rejection.

3. The Combination of Hampton and Dempski Does Not Disclose or Suggest Each and Every Element of Dependent Claims 15 and 42.

Claims 15 and 42, which are dependent from independent Claims 31 and 33, respectively, are directed to the same subject matter and are therefore being argued together. Claims 15 and 42 recite that the solid preparation further comprises at least one additional layer underlying the continuous film coating layer that comprises a colorant that imparts a colorant to the coating layer that is different from the colors of the overlying continuous film coating layer. Neither Hampton nor Dempski disclose or suggest a tablet/pill having such an intermediate layer. The Examiner has completely failed to cite where this element of Claims 15 and 42 can be found, nor has the Examiner made any attempt to even address the basis for rejecting these claims based on the combination of Hampton and Dempski. Thus, the combination of the references fails to disclose or suggest each and every element recited in Claims 15 and 42.

For the reasons set forth above, Applicants respectfully submit that the combination of Hampton and Dempski fails to disclose or suggest each and every element recited in Claim 33. Applicants respectfully request that the Board overturn this rejection.

4. The Combination of Hampton, Dempski and Hoover Does Not Disclose or Suggest Each and Every Element of Dependent Claims 18 – 20 and 45 - 47.

Hoover describes a caplet wherein a caplet core is encapsulated in a gelatin capsule. The caplet and capsule are of two distinct colors so that the resulting caplet has two colors. Hoover further states that “[i]nsertion of the caplet within one-half of a gelatin capsule also allows for the visual perception of embossed or debossed letters, logos, symbols, and that like that may be placed on the surface of the caplet.” See column 4, lines 37-44. (emphasis added). Hoover does not disclose or suggest a solid preparation having a multicolor continuous film coating and therefore does nothing to overcome the deficiencies of Hampton or Dempski.

Claims 18 – 20, which are dependent from independent Claim 31, and Claims 45 – 47, which are dependent on independent Claim 33 are directed to the same subject matter and are therefore being argued together. Claims 18 and 45 recite that the multicolor coating includes a pattern in the form of a logo; Claims 19 and 46 recite that the coating of the solid preparation includes a pattern in the form of a bar code ; and Claims 20 and 47 recite that the coating of the solid preparation includes a pattern that comprises letters. In all the claims in question, the pattern forming the logo, bar code, or letters is formed by irradiating a portion of the continuous film coating to produce a coating having different colorations. As noted above, Hoover fails to disclose or suggest a continuous multicolored coating. Further, the patterns recited in Claims 18 – 20 and 45 – 47 are part of the coating and are not printed or adhered to the surface of the coating. This is a completely different structure than the caplet of Hoover. Thus, the combination of Hampton, Dempski and Hoover fails to disclose or suggest each and every element recited in Claims 18 – 20 and 45 – 47.

For the reasons set forth above, Applicants respectfully submit that the combination of Hampton, Dempski, and Hoover fails to disclose or suggest each and every element recited in Claims 18 – 20 and 45 – 47. Applicants respectfully request that the Board overturn this rejection.

5. There is no Motivation to Combine the teachings of Hampton and Demski

Applicants respectfully submit that one of ordinary skill in the art would have no motivation to combine Hampton and Demski in the manner contemplated by the Examiner for one or more of the following reasons:

- a. neither Hampton nor Demski provide the necessary motivation;
- b. Demski teach away from the contemplated combination; and
- c. the contemplated combination would render Hampton unsatisfactory for its

intended purpose.

a. Neither Hampton nor Demski Provide any Motivation to combine their teachings as contemplated by the Examiner.

Hampton and Demski fail to provide any motivation to combine their teachings. In the Office Action of October 6, 2006, the Examiner stated that it would be obvious "to incorporate the dye coating material stabilization methods, which comprise the step of exposing pills or tablets to sunlight or ultraviolet radiation taught by Demski et al. within the multi-characteristic, bi-layered, two-colored tablet of Hampton et al. if one would desire a colored change effect observed in the tablet." See page 6. However, there is no disclosure or suggestion in the prior art to provide any motivation to modify Hampton's clear coating layer and to provide differences in coloration in the coating layer rather than the underlying tablet. Hampton clearly teaches that the differences in coloration arise from the core, not the outer coating. For example, Hampton teaches that the tablet includes two distinct color sections 14, 18 that form "halves of tablet core 12." See column 3, lines 10-19 (emphasis added). Further, Hampton teaches that this colored core is coated with a clear material. See column 3, lines 15-16 and column 5, lines 37-49. Thus, nothing in Hampton's teachings would provide motivation to effect discoloration of the coating layer because the Hampton's core already includes the desired color variation. Indeed and as discussed in greater detail below, such modification of Hampton's coating would be undesirable. Demski on the other hand, clearly teaches the prevention of discoloration in the coating by using a dye stabilization compound. Thus, Demski actually teaches how to make a tablet having a mono-colored coating layer, and does not provide motivation for producing a

multicolored tablet, let alone a multicolored coating layer. Thus, neither Hampton nor Dempski provide any motivation that would lead one of ordinary skill in the art to combine their respective teachings.

b. Dempski Teaches Away from the Contemplated Combination.

As discussed above, Dempski specifically teaches fading or discoloration due to ultraviolet exposure as being undesirable. Specifically, Dempski states that “[a] faded or speckled pill or tablet can have an unpleasant psychological effect...” See column 1, lines 32 – 33. Dempski also states that “[p]atients in need of self-administrated medication will often avoid proper treatment if it appears unattractive to them.” See column 1, lines 36 – 38. As a result, one of ordinary skill in the art would not be motivated to expose the tablet/pill of Hampton to ultraviolet light in an attempt to produce a multicolored tablet because Dempski repeatedly emphasizes that such fading/speckling is undesirable and destroys the undesirable appearance of the tablet/pill. In combining Hampton and Dempski, the Examiner has ignored the teachings in the references that teach away from the claimed invention and teach away from the combination of Hampton and Dempski. However, “[it] is improper to combine references where the references teach away from their combination.” See MPEP 2146.

There are absolutely no teachings in either Dempski or Hampton that would lead one to believe that such fading could be considered desirable. In fact, the only possible source for such a suggestion comes from Applicants’ own teachings. It is abundantly clear that the Examiner is using hindsight based on Applicants’ teachings in maintaining the rejections of the claims. This is not the proper analysis for making an obvious rejection.

c. The Contemplated Combination would render Hampton Unsatisfactory for its Intended Purpose.

The rejection of the claims based on the combination of Hampton and Dempski also fails to provide the required expectation of success. Moreover, the person of ordinary skill in the art would perceive just the opposite—an expectation of failure. Modifying Hampton to have the coating of Dempski would render Hampton’s tablet unsatisfactory for its intended purpose

because the color stabilization dye of Dempksi would obscure the multicolored core of Hampton. As stated above, Hampton describes a tablet having a core with two distinct colored sections with a clear demarcation line between the sections. Applying the coating of Dempksi to the core of Hampton would prevent a user of the tablet from seeing the colored sections in the tablet core. As a result, the tablet would be unsatisfactory for its intended purpose because the multicolored core could not be seen. Thus, one of ordinary skill in the art would not be motivated to modify the tablet described in Hampton to have the coating of Dempksi because such a modification would render Hampton unsatisfactory for its intended purpose. Further, the MPEP states that “[r]easonable expectation of success is the standard with which obviousness is determined.” See 2141. The Examiner has ignored this tenant of patent law. As discussed above the references include multiple statements that teach away from any reasonable expectation of success.

Finally, the Examiner has failed to follow the standard for making an obviousness rejection as articulated by the *Supreme Court in Graham v. John Deere*, 383 U.S. 1 (1966) and in section 2141 of the MPEP. The crux of the Examiner’s reasoning is articulated on page 6 of the Office Action. The Examiner states that “the prior art recognizes and teaches a tablet that is multicolored and has two layers that provide for distinct colors with different color sections, provided for easy recognition of the tablet and teaches the concept that exposure of tablets to radiation results in fading or discoloration of tablets.” In other words, the Examiner is reasoning that the claimed invention is obvious because (1) two colored tablets are known and (2) it is known that UV radiation causes fading. This can surely not be the standard by which proper rejections are made.

According to *Graham*, an obviousness analysis includes: (A) determining the scope and contents of the prior art; and (B) ascertaining the differences between the prior art and the claims in issue. See MPEP 2141. The Examiner has failed to do both of these. First, the Examiner has failed to understand the scope and contents of the prior art. As discussed above, Dempksi teaches a dye coating that is stabilized; not a multicolored coating. Further, Dempksi teaches that fading or discoloration of the coating is undesirable; this teaching was completely ignored by the Examiner. Hampton teaches a clear coating with a core that is multicolored; Hampton does not teach a multicolored coating. Second, the Examiner has failed to ascertain the

differences between the prior art and the claimed invention. Hampton teaches how to obtain a multicolored tablet by using a multicolor core. Dempski teaches a tablet having a coating that includes a dye to resist color fading. As noted above; neither Dempski nor Hampton teaches a multicolored coating. In contrast, the claimed invention recites a tablet having a multicolored continuous coating, which is not taught in Hampton or Dempski. Thus, the Examiner has failed to compare the actual teachings of the references to the claims.

The MPEP further states that in making an obvious rejection “the references must be considered as a whole and must suggest the desirability . . . of making the combination.” See MPEP 2141. The Examiner has also failed to adhere to this tenet of patent law. As discussed above, there are no teachings in the cited references that would motivate one to combine the coating of Dempski with the multicolored core of Hampton, and the Examiner has failed to articulate a reasonable motivation for making such a combination. Further, the Examiner’s arguments show that he has based the rejection on what he perceives as the “gist” of the invention, i.e., a two-colored tablet rather than on the structural features recited in the claims. However, the Examiner’s analysis reasoning completely ignores the claim language and fails to consider the invention as a whole. See MPEP 2141.02.

The Office Action further asserts that the Applicants have failed to demonstrate that the claimed invention has any unexpected or surprising results. However, such a demonstration is unnecessary because the Office has failed to establish a *prima facie* case of obviousness.

From the above discussion, it can be seen that the Examiner has repeatedly failed to follow the standards laid out by the Supreme Court and the MPEP in making an obviousness inquiry. A proper analysis shows that the claimed invention is neither taught nor suggested by the cited references.

8. ***Claims Appendix.***

An appendix containing a copy of the claims involved in the appeal.

9. ***Evidence Appendix.***

No evidence has been submitted to the Examiner or relied upon by the Appellant.

10. ***Related Proceedings Appendix.***

There are not decisions by a court of the Board in related proceedings.

CONCLUSION

In view of the foregoing arguments, Appellant respectfully submits that Claims 6 – 9, 11, 13 – 20, and 31 – 47 are patentable over the cited references. A decision from the Board of Patent Appeals and Interferences reversing the final rejection of the pending claims is therefore earnestly solicited.

Respectfully submitted,



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CLAIMS APPENDIX

- 1 – 5. Cancelled.
6. (Previously Presented) The solid preparation of claim 31, wherein said solid preparation is a tablet.
7. (Previously Presented) The solid preparation of claim 31, wherein said continuous film coating layer comprises one or more cellulose derivatives as film coating agents.
8. (Previously Presented) The solid preparation of Claim 7, wherein said cellulose derivative is selected from the group consisting of hydroxypropyl methyl cellulose (HPMC), methylcellulose (MC) and hydroxypropyl cellulose (HPC).
9. (Previously Presented) The solid preparation of Claim 8, wherein said cellulose derivative is hydroxypropyl methyl cellulose.
10. Cancelled.
11. (Previously Presented) The solid preparation of claim 31, wherein at least a portion of said film is exposed to radiation under conditions sufficient to fade the exposed colorant.
12. Cancelled.
13. (Previously Presented) The solid preparation of claim 31, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant semi-transparent.

14. (Previously Presented) The solid preparation of claim 31, wherein said colorant is a food additive.

15. (Previously Presented) The solid preparation of claim 31, wherein said solid preparation further comprises at least one additional layer underlying said continuous film coating layer, said at least one additional layer comprising a colorant to impart a color thereto that is different from the colors of the overlying continuous film coating layer.

16. (Previously Presented) The solid preparation of claim 31, wherein said film coating layer has two or more different colors.

17. (Previously Presented) The solid preparation of claim 31, wherein said film coating layer has a pattern of two or more different colors.

18. (Previously Presented) The solid preparation of claim 17, wherein said pattern comprises a logo.

19. (Previously Presented) The solid preparation of claim 17, wherein said pattern comprises a bar code.

20. (Previously Presented) The solid preparation of claim 17, wherein said pattern comprises letters.

21 – 30. Cancelled.

31. (Previously Presented) A solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of
coating a solid preparation with a continuous film coating layer having one or more colorants; and,

exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

32. (Previously Presented) The solid preparation of claim 31, wherein at least a portion of said film coating layer is exposed to radiation under conditions sufficient to render the exposed colorant transparent.

33. (Previously Presented) A solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of

coating a solid preparation with a continuous film coating layer having one or more colorants; and,

changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer to the exclusion of the remainder of the coating.

34. (Previously Presented) The solid preparation of claim 33, wherein said solid preparation is a tablet.

35. (Previously Presented) The solid preparation of claim 33, wherein said continuous film coating layer comprises one or more cellulose derivatives as film coating agents.

36. (Previously Presented) The solid preparation of Claim 35, wherein said cellulose derivative is selected from the group consisting of hydroxypropyl methyl cellulose (HPMC), methylcellulose (MC) and hydroxypropyl cellulose (HPC).

37. (Previously Presented) The solid preparation of Claim 36, wherein said cellulose derivative is hydroxypropyl methyl cellulose.

38. (Previously Presented) The solid preparation of claim 33, wherein at least a portion of said film is exposed to radiation under conditions sufficient to fade the exposed colorant.

39. (Previously Presented) The solid preparation of claim 33, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant transparent.

40. (Previously Presented) The solid preparation of claim 33, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant semi-transparent.

41. (Previously Presented) The solid preparation of claim 33, wherein said colorant is a food additive.

42. (Previously Presented) The solid preparation of claim 33, wherein said solid preparation further comprises at least one additional layer underlying said continuous film coating layer, said at least one additional layer comprising a colorant to impart a color thereto that is different from the colors of the overlying continuous film coating layer.

43. (Previously Presented) The solid preparation of claim 33, wherein said film coating layer has two or more different colors.

44. (Previously Presented) The solid preparation of claim 33, wherein said film coating layer has a pattern of two or more different colors.

45. (Previously Presented) The solid preparation of claim 44, wherein said pattern comprises a logo.

46. (Previously Presented) The solid preparation of claim 44, wherein said pattern comprises a bar code.

47. (Previously Presented) The solid preparation of claim 44, wherein said pattern comprises letters.